510(K) #: K021323

510(K) SUMMARY

10.1 SUBMITTER INFORMATION

A.	Company Name:	IntraLuminal Therapeutics, Inc.
B.	Company Address:	6354 Corte Del Abeto – Suite A Carlsbad, CA 92009
C.	Company Phone:	(760) 918-1820
D.	Company Facsimile:	(760) 603-9615
E.	Contact Person:	Pamela Misajon Vice President of Regulatory Affairs and Quality Assurance

10.2 DEVICE IDENTIFICATION

A.	Device Trade Name:	Safe-Steer™ Guide Wire System
C.	Device Common Name:	Catheter Guide Wire
D.	Classification Name:	Catheter Guide Wire
E.	Device Class:	Class II (per 21 CFR 870.1330)

10.3 IDENTIFICATION OF PREDICATE DEVICE

The predicate device is the Safe-Steer™ Guidewire System, manufactured by IntraLuminal Therapeutics and cleared under Premarket Notification 510(k) K011986.

10.4 DEVICE DESCRIPTION

The Safe-Steer™ Guide Wire System consists of the following:

- Safe-Steer™ 0.014" Guide Wire
- Safe-Steer™ OCR Unit with Display Monitor

The Safe-Steer™ Guide Wire is similar to a conventional 0.014" coronary guide wire, except that it incorporates an optic fiber, which runs the length of the guide wire. The Safe-Steer™ Guide Wire is connected to the OCR Unit, providing information on the Display Monitor of the location of the distal tip relative to the vessel wall.

10.5 INTENDED USE

The Safe-Steer™ Guide Wire System is indicated for use in facilitating the placement of catheters used in percutaneous interventions in native coronary arteries with total occlusions.

10.5 TECHNOLOGICAL CHARACTERISTICS

The Safe-Steer™ Guide Wire is similar in basic materials, design, construction and mechanical performance to the predicate device.

10.6 BIOCOMPATIBILITY AND PERFORMANCE DATA

The materials used to manufacture the patient contact components of the Safe-Steer Guide Wire have been subjected to biocompatibility testing in accordance with ISO 10993-1 and relevant FDA Guidance to ensure biological safety for the intended use.

The Safe-Steer Guide Wire has been subjected to performance testing to verify conformance to the requirements of the product specification.

Testing has been conducted in accordance with the Design Control Procedures of the company as required by the Quality System Regulation (21 CFR 820).

10.7 CONCLUSIONS DRAWN FROM STUDIES

On the basis of the testing conducted on the Safe-Steer™ Guide Wire it may be concluded that the device satisfies safety and performance requirements when used in accordance with the Instructions for Use for the indicated patient population. The Safe-Steer™ Guide Wire is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2002

Ms. Pamela Misajon
IntraLuminal Therapeutics, Inc.
6354 Corte Del Abeto, Suite A
Carlsbad, CA 92009

Re: K021323
SAFE-STEER™ Guide Wire System
Regulation Number: 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: April 25, 2002
Received: April 26, 2002

Dear Ms. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: ~~K011986~~ K021323

Device Name: Safe-Steer™ Guide Wire System

Indications For Use: **The Safe-Steer™ Guide Wire System is indicated for use in facilitating the placement of catheters used in percutaneous interventions in native coronary arteries with total occlusions.**

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021323

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)